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In the Supreme Court of the United States

OCTOBER TERM, 1947

No. 577

UNITED STATES OF AMERICA, PETITIONER

v.

FRED URBETEIT, CLAIMANT OF 16 ARTICLES OF DEVICE MORE OR LESS, LABELED "SINUOTHERMIC," ETC.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE FIFTH CIRCUIT

The Solicitor General, on behalf of the United States, prays that a writ of certiorari issue to review the judgment of the United States Circuit Court of Appeals for the Fifth Circuit, reversing the judgment of the District Court of the United States for the Northern District of Florida condemning certain devices as misbranded under Section 304 of the Federal Food, Drug, and Cosmetic Act.

OPINION BELOW

The opinion of the circuit court of appeals (R. 179–183) is reported in 164 F. 2d 245.

JURISDICTION

The judgment of the circuit court of appeals was entered November 7, 1947 (R. 183). The jurisdiction of this Court is invoked under Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1945.

QUESTIONS PRESENTED

1. Whether leaflets claiming diagnostic capabilities and therapeutic values for machines transported in interstate commerce could be considered as printed or graphic matter "accompanying" the machines, and thus constituted "labeling" within the meaning of Section 201 (m) of the Federal Food, Drug, and Cosmetic Act, where the leaflets were shipped separately from the machines but were supplied by the shipper to the consignee for the purpose of explaining to purchasers and renters of the machines, and prospective patients, the usefulness of the machines.

2. Whether printed and graphic matter shipped to explain the uses to be made of the machines, which information was given nowhere else in the labeling, constitutes "labeling" within the meaning of the Act even though it may also constitute advertising.

3. Whether the Government was entitled to a decree of condemnation because of false claims of diagnostic capabilities despite alleged errors in exclusion of evidence offered to show the claimed therapeutic values of the machines.

STATUTE INVOLVED

The Federal Food, Drug and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, et seq.), provides in pertinent part:

> SEC. 201. For the purposes of this Act—
>
> * * * * *
>
> (h) The term "device" * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; * * *
>
> (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.
>
> SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *
>
> SEC. 502. A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.

STATEMENT

On January 9, 1947, a second amended libel of information was filed in the United States District Court for the Northern District of Florida, under Section 304 of the Federal Food, Drug, and Cosmetic Act, seeking the seizure and condemnation of 16 "articles of device" labeled "Sinuothermic" (R. 11–15). The libel alleged that the device was misbranded within the meaning of Section 502 (a) when introduced into and while in interstate commerce in that representations made in a leaflet entitled "The Road to Health," relative to the curative and therapeutic powers of the device in the diagnosis, cure, mitigation, treatment, and prevention of disease, were false and misleading. It was charged that the leaflet had accompanied the device in interstate commerce (R. 13).

Fred Urbeteit, the respondent, who is a naturopathic physician (R. 119), appeared as claimant of ten of the devices of the so-called treating unit type (R. 5, 12, 10), and J. J. H. Kelsch, an unlicensed naturopathic and chiropractic physician (R. 32), appeared as claimant of the remainder of the devices, two of which were the so-called master units and four of which were of the treating unit type (R. 5, 12, 10). Together they filed a "consent to amendment and claim" which admitted factual recitals in previous pleadings, renewed the statements of ownership, ad-

mitted that the devices and leaflets had been shipped in interstate commerce, but denied that they were shipped together or that they related to each other, and neither admitted nor denied the dates of the shipments because of lack of exact knowledge. They also denied that the leaflets accompanied the devices in interstate commerce and that the representations made in the leaflets were false or misleading (R. 10–11, 11–15).

The case was tried to the court without a jury (R. 15). The claimants' answer admitted that the sixteen devices and a number of leaflets, entitled "The Road to Health," were introduced into interstate commerce at Tampa, Florida, for shipment to Cincinnati, Ohio, and were in possession of Kelsch at Cincinnati when the libel was filed (R. 10, 13–14). The evidence showed that the respondent was the shipper (R. 24, 29–31). Four shipments of the devices were made by means of the facilities of the Railway Express Agency, the first on July 25, 1945, the second on August 14, 1945, the third on August 18, 1945, and the fourth on September 21, 1945 (R. 24–25).

Kelsch testified that he had received a course of instruction from the respondent in Florida some time in June 1945, and that he had remained there approximately three weeks (R. 25–26). While there, arrangements were made for the purchase of some devices and for the rental of others, contingent upon Kelsch's ability to make financial arrangements in Cincinnati (R. 29).

As a part of the same transaction, respondent agreed to supply a quantity of the leaflets, "The Road to Health," for the purpose of explaining the machines to Kelsch's patients (R. 29). Accordingly, the leaflets were shipped to Kelsch in bulk supply and received by him. Pursuant to an understanding between Kelsch and respondent, some of the leaflets were mailed out to patients and others were shown to patients during consultation (R. 29-30).

Kelsch first testified that he received the leaflets, by parcel post, after the machines were shipped to him (R. 29, 6), but on closer examination it appeared that he did not know the exact date the leaflets were received. He stated that they were received sometime around September (R. 31). Some of the leaflets were found on September 5, 1945, in and on a desk in Kelsch's main consulting room within the reach and view of patients who consulted with him there. The devices were in the adjoining consulting rooms and treating rooms. The devices bore a label which contained the statement "U. S. Patent Sinuothermic Trade Mark" together with a serial number (R. 20), and no other labeling except for "The Road to Health" was delivered to the consignee.

In addition to many representations of therapeutic value involving, among many others (see R. 165), such varigated diseases as cancer, tuberculosis, diabetes, appendicitis, heart disease, hay

fever, infantile paralysis, menstrual discomfort, peritonitis, and nervousness, the leaflet, "The Road to Health," in part describes the diagnostic capabilities of the machines as follows:

IMPORTANCE OF EXAMINATION

You must realize the all importance of being examined the Sinuothermic way, which leaves out all guess work as Sinuothermic locates the cause and registers exactly [p. 1, col. 3].

* * * * *

CANCER DANGER SIGNAL

* * * At the Sinuothermic Institute no one is ever treated without first being thoroughly examined, and it should be remembered that NO really COMPETENT doctor will treat a condition that might be a cancer without first making a careful examination. INSIST on a thorough examination no matter who your doctor is. Be examined with Sinuothermic which registers exactly and never makes a mistake [p. 1, col. 4].

* * * * *

BE EXAMINED

Why have someone guess *at what your ailment is* when at the Sinuothermic Institute, Inc., you can be examined with that never failing Sinuothermic machine which leaves out all guess work and registers exactly [p. 1, col. 4]. [Italics added.]

* * * * *

SINUOTHERMIC EXAMINATION

> Dr. Urbuteit told them that he could not tell them anything until he examined her with Sinuothermic. The examination revealed that she not only had a tumor in the uterus but she was also pregnant about 5 months * * * [p. 2, col. 6].
>
> * * * * *

SCIENCE AT ITS PEAK

> Sinuothermic is the last word in scientific discoveries. Sinuothermic is a tester of human tissue. You could liken Sinuothermic to the tester they use to test your radio tubes with * * * Sinuothermic registers exactly the condition of human tissue [p. 2, col. 6].

There are many other representations in the leaflet[1] which represent that the machine is capable of locating the cause of any ailment and registering exactly.

The evidence at the trial disclosed that the Sinuothermic machine is designed to draw electricity from an ordinary household wall socket, to control the full line voltage (electrical pressure) by turning in variable amounts from zero to the full line voltage (115–120 volts), to step this voltage down to a maximum value of 60 volts, and to deliver current to the patient so as to flow

[1] This exhibit (R. 13, 19), which was before the Circuit Court of Appearls, is on file with the Clerk of this Court.

through the body between two pad electrodes that are applied to the bare skin (R. 39–44, 50–52, 164). The small machines differed from the master units only in the omission of the four indicating meters (R. 43, 164).

The Government's evidence showed that even the master model which had four indicating meters, was incapable of registering any pathological changes in the body. This because the meters were primarily affected by the patient's resistance to electrical current and because internally the current is conducted through body fluids and not body tissues (R. 43, 51–52). The so-called treating units did not have the four indicating meters (R. 43). The expert testimony for the Government was that these machines were without value in the diagnosis of the disease conditions involved (R. 72, 76, 79–80, 83–85, 88–89, 91, 93, 96–97, 99, 100, 104–105, 109–112).

Urbeteit undertook a description of his method of diagnosis at the trial (R. 126–127, 128–130). He said that when the current from the machine encounters a lesion in the human body the meters will register "the amount of intensity or resistance there is in that particular area" (R. 127, 128–129). He then stated, however, that:

> *The meters do not tell me what the ailment is,* it merely registers when it is below normal. If it is normal it has a free flow; if it is not normal it has the obstructed flow, and according to the amount of ob-

> struction that also indicates the severity of the ailment itself. Then the doctor, himself, should know from other tests what the ailment is * * * R. 129.
>
> * * * * *
>
> * * * There is no way of registering the kind of ailment or the name of an ailment. It merely locates where there is something wrong. Then whatever that something is wrong it is necessary then to take chemical tests; or whatever tests is necessary to determine the name of the ailment that can also be done. *But I find in all my experience it is not necessary to go to all that trouble to take those tests.* As long as the patient gets well, that seems to be the first requisite (R. 129–130). [Italics added.]

The testimony admits that the machines alone are incapable of diagnosing disease.

The trial court found (1) that the leaflets entitled "The Road to Health" accompanied the devices while in interstate commerce (R. 164); (2) that the leaflets claimed diagnostic values and therapeutic effects for the machines in many conditions (R. 165, Finding 4) and that they represented that the machine will register the exact nature of any disease (R. 165, Finding 5); (3) that the master model was incapable of diagnosing disease by registering pathological changes in the body (R. 165–166, Finding 5); and (4) that the principles on which the machines were claimed to operate were impossible of practical application with these instruments (R. 166, Finding 7).

The falsity of the claims of diagnostic capabilities for the small models was treated under the general finding last mentioned. The court also found that the claims of therapeutic and curative effect were false and misleading (R. 166). The court concluded that the devices had been shipped in interstate commerce and were misbranded, and that petitioner was entitled to a decree of condemnation (R. 167), which was entered on January 27, 1947 (R. 168-169).

Upon appeal to the Circuit Court of Appeals for the Fifth Circuit, by Urbeteit alone, the judgment was reversed and the cause remanded for further proceedings (R. 179–183) on the grounds that the leaflets had not accompanied the devices while in interstate commerce and, hence, did not constitute labeling within the meaning of the Act,[1] and that the trial court had erred in refusing to hear certain testimony.[2]

---

[1] Although it did not expressly so hold, the court indicated doubt that the leaflets could properly be considered as in the nature of labeling for the machines because it thought the leaflets to be advertising (R. 181–182).

[2] The trial court excluded the testimony as to diagnoses made by the respondent because it thought that the diagnoses were based upon the machine examination (R. 131, 159, 161, 163). The Circuit Court of Appeals interpreted the record as showing that respondent used all known methods of diagnosis (R. 182). The trial court excluded testimony of respondent's patients as to the benefits they had received through use of the device because it thought it was offered (1) as opinion evidence on medical questions and was thus incompetent, or (2) as hearsay evidence as to what some physician not in attendance at the trial had told the patients

SPECIFICATION OF ERRORS TO BE URGED

The Circuit Court of Appeals erred:

1. In reversing the judgment of the district court.

2. In holding that the leaflets "The Road to Health" did not "accompany" the devices, within the meaning of Section 201 (m) of the Act.

3. In failing to affirm the judgment of the district court because of false and misleading claims of diagnostic capabilities despite alleged errors in exclusion of evidence offered to show the claimed therapeutic values of the machines.[3]

REASONS FOR GRANTING THE WRIT

1. (a) Section 201 (m) provides that—

> (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

This case presents for the first time in this Court the question of the proper interpretation of the

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as to their diseases (R. 160–163). The Circuit Court of Appeals held that the witnesses should have been permitted to state whether their external symptoms abated and their pains ceased (R. 182–183).

[3] Error is not assigned as to the rulings below with respect to the exclusion of evidence by the trial court. For reasons hereinafter set forth (pp. 18-21), petitioner submits that even if the court below did not err in holding the excluded evidence admissible, petitioner is entitled to a judgment of condemnation because of admittedly false representations on an issue to which the excluded evidence did not pertain.

phrase "accompanying such article". The opinion of the Circuit Court of Appeals holds that the leaflets in question did not "accompany" the machines because they were not shipped substantially simultaneously. As we read the opinion below, it decides that the labeling and the device or article must go along with each other in a physical sense; that the two must be shipped or received at or about the same time; that such a construction is required because "in a criminal and forfeiture statute the meaning cannot be stretched" (R. 180–181).

This holding is in direct conflict with the decision of the Circuit Court of Appeals for the Seventh Circuit in *United States* v. *Kordel*, decided November 6, 1947, not yet reported.[4] That opinion is set forth in the Appendix, *infra*. The test there applied was not "physical contiguity" in shipment or receipt,[5] but the relationship of the literature to the product. Was the literature to be utilized with the product to inform the purchasing public of its uses and purposes? See also *United States* v. *7 Jugs, etc., of*

[4] We are advised that a petition for certiorari will be filed in the *Kordel* case.

[5] In the *Kordel* case, it was pointed out in the opinion that "In some cases [the literature] was contained in the carton in which the articles were shipped. More often, it was separately shipped to the same consignees, and, in at least one case, a period of a year and a half intervened between the shipment of the product and the literature, respectively."

Dr. Salsbury's Rakos, 53 F. Supp. 746 (D. Minn.).[*] It is the Government's position that it is not necessary that descriptive literature be shipped in the same container with, or at the same time as, the article to which it relates in order for the literature to constitute labeling "accompanying" an article within the meaning of the Act. Rather, the relevant factors are interdependence of the literature and the article, their common origin, destination, display and distribution, and their purpose and use together.

(b) The interpretation of the phrase "accompanying such article" is of vital importance in the enforcement of the Federal Food, Drug, and Cosmetic Act. Since the enactment of the law, it has become a common practice to ship articles separately from leaflets, circulars, and booklets containing false and fantastic claims of diagnostic capabilities and therapeutic values, in studious attempts to evade the Act. As soon as one plan to escape the statutory ban is met, another is concocted by the purveyors of false nostrums and panaceas. If such evasive schemes can be successfully perpetrated, the salutary purpose of the Act will be defeated. The decision of the Circuit Court of Appeals will, at least in the Fifth Circuit, prevent the statute from being invoked

[*] *Alberty* v. *United States*, 159 F. 2d 278 (C. C. A. 9), upon which the court below largely relied, was, as the opinion in that case discloses, complicated by deficiencies in the information which was attacked.

against fraudulent and dangerous drugs and devices so long as their distributors utilize the simple scheme of seeing to it that the article is shipped apart from the labeling. Considering the remedial purposes of the Act, and the reasons for its enactment (*United States* v. *Dotterweich*, 320 U. S. 277, 280; *United States* v. *Sullivan*, No. 121, decided January 19, 1948), it is clear that Congress did not intend to permit any such evasion of the statutory requirements.

2. These leaflets were by nature "labeling" notwithstanding they also constituted advertising. The leaflets in the instant case were prepared by the respondent, and were supplied by him to the consignee for the purpose of explaining to prospective purchasers, renters, and patients the usefulness of the device and how it is employed in the diagnosis, cure, mitigation, and treatment of various diseases. Without the leaflets the devices lacked labeling in that nowhere else was this essential information supplied. The label of the devices bore only "U. S. Patent Sinuothermic Trade Mark" (R. 20). Obviously such a label does not explain the purposes for which the device was intended to be used, but the leaflet did contain that information in elaborate detail. Thus, the leaflets were intended to and did serve the purposes of labeling equally as much as if they had been physically attached to the machines. Without the extravagant claims made in the leaflets it

is doubtful that the devices could be rented or sold or that the services of the machines could have been sold to patients.

It was the purpose of Congress in enacting the Federal Food, Drug, and Cosmetic Act in 1938 to include promotional material of this kind within the definition of labeling. The Food and Drugs Act of 1906, as amended [21 U. S. C. 10 (1934 ed.)], provided that a drug was to be deemed misbranded "If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent." The word "contain" was specifically inserted by amendment in 1912 to cover circulars or printed matter placed inside the package. *Seven Cases of Eckman's Alterative* v. *United States*, 239 U. S. 510. Nothwithstanding the 1912 Amendment, unscrupulous purveyors of nostrums were able readily to circumvent the law by adopting the practice of shipping, separate from the drug to which it related and which it described, literature containing false and fraudulent claims.

Thus, prior to 1938, the law protected the public only where false claims were made on the label or package or on circulars within the package. The terms of the old law were well designed to accomplish that purpose, and Congress in the new law could have employed the same language if it had

intended no greater coverage.[7] It was apparent, however, that there was need for extending the consumer protection to items of labeling which occurred outside the package. The law was changed therefore to include any "written, printed or graphic matter upon * * * or *accompanying* any article."

Walter G. Campbell, then Chief of the Food and Drug Administration, explained the purpose of the definition at the Hearings Before a Subcommittee of the Committee on Commerce, United States Senate, Seventy-Third Congress, Second Session, on S. 1944, p. 16:

> At the present time the law has control over those statements that are attached to or that accompany the package in the form of circulars. For the purposes of the subsequent requirements of this bill these have been divided into two classes; first, "label" meaning the principal label or labels upon the immediate container of any food, drug, or cosmetic, and upon the outside container or wrapper, if any there be, of the retail package of any food, drug, or cosmetic. Then the term "labeling" is defined so as to include not only the label but all circulars and material and placards for display purposes and the like that may in any form whatever accompany the article of food, drug,[8] or cosmetics.

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[7] Cf. *United States* v. *Walsh*, 331 U. S. 432.

[8] Devices were included within the definition of drug in this bill (Section 2 (b)).

The fact that the leaflet "The Road to Health" has some of the characteristics of advertising does not exclude it from the definition of labeling under the Act. *United States* v. *Research Laboratories,* 126 F. 2d 42 (C. C. A. 9), certiorari denied, 317 U. S. 656; *United States* v. *Lee,* 131 F. 2d 464 (C. C. A. 7). An item of literature of this kind may at once serve the dual purpose of advertising and labeling. In the *Research Laboratories* case, the court said (p. 45):

> Appellee contends that the circulars constituted advertising and, therefore, did not constitute labeling within the meaning of the Act. The contention assumes that printed matter (such as a circular) cannot constitute both advertising and labeling. This assumption is unwarranted. Most, if not all, labeling is advertising. The term "labeling" is defined in the Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.

3 (a). The evidence which the Circuit Court of Appeals held the District Court to have improperly excluded did not relate to the false representations as to the diagnostic capacity of the machines but to the alleged misrepresentations as to curative value. The misrepresentations as to diagnostic capacity were established by respondent's own admission, *inter alia.* Thus, any error in the exclusion of evidence which did not

disprove the making of such misrepresentations would not defeat the Government's right to condemnation.

The Statement sets forth some of the claims of diagnostic capabilities made for the devices by the leaflets (*supra*, pp. 7–8). The trial court found that these claims represented that the devices would register the exact nature of any disease and would diagnose diseases (R. 165, Findings 4–5). Urbuteit's testimony was that the machines—even the ones that had meters—would not register what the patient's ailment was (R. 129–130). He said that the device "merely locates where there is something wrong." The Government's evidence was overwhelming that the machines could not do even that. The Circuit Court of Appeals pointed out that the respondent's testimony "only claimed the machine to be an aid in diagnosing." His testimony was that the machine "only located the spot where the abnormal tissue was" after which "it was then a matter of judgment as to what the disease was" (R. 182).

The labeling claims are irreconcilable with this testimony. They assert that the machine "leaves out all guess work"; that it "registers exactly and never makes a mistake"; and that it removes the necessity of having "someone guess at what your ailment is." See pp. 7–8, *supra*. Respondent's testimony implicitly admitted that

those claims are falsehoods. The Government's evidence gave them the lie explicitly.

Under the Federal Food, Drug, and Cosmetic Act it is not necessary that the Government prove that the labeling representations are false and misleading in all respects. Petitioner is entitled to a decree of condemnation if it shows that any one of the various claims made in the labeling is either false or misleading in any particular. Section 502 (a); *Goodwin* v. *United States*, 2 F. 2d 200, 201 (C. C. A. 6); *United States* v. *Six Dozen Bottles, etc.*, 158 F. 2d 667, 669–670 (C. C. A. 7); and *United States* v. *One Device * * * Colonic Irrigator*, 160 F. 2d 194, 200 (C. C. A. 10).

The evidence that was excluded was offered to prove that claims of therapeutic or curative value made for the machines were true (R. 158–163). The Circuit Court of Appeals concluded that the evidence from respondent as to his diagnoses was erroneously excluded because the diagnoses had not been made solely by the machine.[9] It concluded also that the testimony of the lay witnesses was erroneously excluded because they should have been permitted to state whether their external symptoms abated and their pains ceased (R. 182–183). The admission of the evidence

[9] The record makes it clear that this testimony was offered to show the diseases which respondent's patients would testify were cured by use of the machine. See R. 158, 160–161, 162–163.

within those limits would have had no bearing upon the diagnostic capabilities of the machines.

Since it appears from the undisputed testimony and from the admissions of the respondent that the machines are incapable of diagnosing disease, and since the machines were represented as having diagnostic capabilities, petitioner is entitled to a decree of condemnation if it prevails on the "accompaniment" issue, irrespective of whether the court below was correct in holding other evidence relating to the curative value of the machines improperly excluded.

(b) Furthermore, the decision below on the accompaniment issue necessarily calls for a dismissal of the libel. If the court below was wrong on that point but correct in reversing the judgment because of the exclusion of evidence, respondent would at most be entitled to a new trial at which the excluded evidence could be admitted.

CONCLUSION

The primary question here presented is one of importance in the administration of the Federal Food, Drug, and Cosmetic Act. The decision below enables unscrupulous distributors of medical devices to introduce their wares into interstate commerce unhampered by the Act through the simple expedient of separating the product and the false representations during interstate transportation. The decision below, if permitted to

stand, will impair the health and lives of many persons who will rely upon this type of fraudulent device instead of obtaining competent diagnoses of serious diseases. There is a conflict in the decisions of the Circuit Courts of Appeals. We respectfully submit that this petition for a writ of certiorari should be granted.

PHILIP B. PERLMAN,
Solicitor General.

FEBRUARY 1948.

APPENDIX

In the United States Circuit Court of Appeals for the Seventh Circuit

No. 9151—October Term and Session, 1947

THE UNITED STATES OF AMERICA, PLAINTIFF-APPELLEE

vs.

LELORD KORDEL, DEFENDANT-APPELLANT

Appeal from the District Court of the United States for the Northern District of Illinois, Eastern Division

November 6, 1947

Before EVANS and SPARKS, *Circuit Judges,* and LINDLEY, *District Judge*

SPARKS, *Circuit Judge.* Appellant was charged by three criminal informations with violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. sections 301, *et seq.* He waived jury trial and, upon trial by the court, was found guilty and fined $200 on each of the twenty counts contained in the three informations. The appeal is from those judgments.

The facts as to the shipping of the drugs and the literature alleged to constitute the misbranding charged in the informations were entirely stipulated. Error is asserted in the court's find-

ing that that literature "accompanied" the drugs in interstate commerce in the purview of the Act prohibiting the introduction or delivery for introduction of any drug that is misbranded. Other contested issues relate to the degree of proof necessary in a criminal proceeding under the Act, whether the Act should be strictly construed, and whether prosecution should have been by indictment rather than by information.

Appellant is a self-styled authority on nutrition and vitamins. He testified that he had written many papers on the subject of vitamins, herbs, minerals, and nutritional diet subjects in general, securing the material for preparation of his papers from books. Operating under various trade names, he had been producing and marketing his own products since January 1941, largely through "health food" stores. The products appear to be, for the most part, compounded of various vitamins, minerals, and herbs. No charge of falsehood is made as to the principal labels printed on the packages in which each is contained. These labels give the name of the article and distributor, content, recommended dosage; and, in some cases, the alleged daily minimum requirement of the vitamins or minerals therein. Otherwise they give no indication as to their intended uses.[1] The misbranding charged is contained in a number of printed pamphlets and circulars, and one display placard. The modes of distribution of this literature differed as charged

[1] The articles involved in the three informations are named "Gotu Kola," "Minerals plus Chlorophyll and Vitamin D," "Cetabs," "Fenugreek Tea," "Fero-B-Plex," "Bolax," "Ormotabs," "Ribotabs," "Kordel Tablets," "Everm," "Kordel A," "Garlic Plus," "Niamin," and "Sarsaparilla Tea."

in the various counts of the informations. In some cases it was contained in the carton in which the articles were shipped. More often, it was separately shipped to the same consignees, and, in at least one case, a period of a year and a half intervened between the shipment of the product and the literature, respectively.

Section 301 of the Food and Drugs Act as amended in 1938, 21 U. S. C. A. sec. 331, prohibits the introduction or delivery for introduction into interstate commerce of any drug that is misbranded; section 502, 21 U. S. C. A. sec. 352, provides that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular; and section 201 (m), 21 U. S. C. A. sec. 321 (m), defines the term "labeling" to include all labels and other written, printed, or graphic matter "(1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

It is now generally held that in order to support a misbranding charge under the Act as amended and revised in 1938, it is not necessary that the matter alleged to accompany the product be shipped in the same container (*United States* v. *Research Laboratories,* 126 F. 2d 42), nor even that it be shipped simultaneously (*United States* v. *Lee,* 131 F. 2d 464; *United States* v. *7 Jugs * * * Rakos,* 53 Fed. Supp. 746; *United States* v. *Paddock,* 67 Fed. Supp. 819).

Appellant contends that the cases referred to are not applicable for the reason that all involved civil proceedings rather than criminal, and further, that the literature here involved was not only not shipped in the same carton with the

products in all cases, but neither was it intended by him that product and literature should be placed together by the dealer to whom they were sent. His theory apparently is that the matter was not intended for labeling, but for advertising. He points to the fact that all of the printed matter was intended either to be mailed out or to be sold, as indicated by the fact that with the exception of the one display placard, each piece either contained a price mark or a mailing permit with space for address. This, he contends, supports his theory that product and literature were not to be distributed together, hence cannot be said to accompany each other.

We find two answers to this contention. In the first place, labeling and advertising are not mutually exclusive, and the same matter may serve both purposes. As the Court of Appeals for the Ninth Circuit states in *United States* v. *Research Laboratories,* 126 F. 2d 42, "Most, if not all, labeling is advertising. The term 'labeling' is defined in the Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising." See also *United States* v. *Paddock,* 67 Fed. Supp. 819. In the second place, the placing of the mailing permit or the price tag on the literature cannot insulate appellant from liability for introducing the drugs and their related descriptive matter into interstate commerce together by consignment to the same consignee for distribution by him. The evidence is clear that the booklets were actually displayed on racks close to the counter where the products were sold and that they were necessary

to inform the purchasing public of the uses to which these products were to be put.

We agree with appellee that "the correct concept of 'accompaniment' is one of a commercial or business association." As stated in the *Rakos* case, *supra,* "misbranding has true significance only in terms of the consumer. * * * 'Accompany' as used in this Act is used to describe a relationship between an article of drug and its labeling. Since there 'can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates' (citing the decision of this court in *United States* v. *Lee, supra*) the booklets here involved should be scrutinized from this viewpoint. In the sense just stated, if the booklets are not labeling, then the products * * * have none."

We, too, are convinced that the test is not of physical contiguity but of textual relationship. Viewed thus, the products and literature here involved were interdependent because without the latter, the former lacked the labeling necssary to inform the purchasing public of their uses and purposes—it is significant that the labels printed on the immediate containers did not indicate the purposes for which the articles were to be used. Hence, the literature was intended and essential to explain the alleged uses of the products. They constituted a supplement to the label physically attached to the product container. One of the health-food dealers in whose store the Kordel products were sold admitted that if he were buying one of the products he would have to go to "reliable sources" to know to what use to put

the product. Presumably those reliable sources were the booklets displayed in racks close by the counter where the drugs were dispensed or lying on the counters where they were available to the public and could be picked up and examined. Some also were wrapped with merchandise or handed to customers.

We agree with the District Court that, because the literature was shipped by appellant or at his order, to the same consignees as the products, related to those products, and was intended to be distributed in relation to them, it did accompany the products into interstate commerce within the definition of the Act. To hold otherwise would be to permit evasion of the Act by the very easy subterfuge of printing a purchase price or a mailing permit on advertising matter otherwise unquestionably accompanying products into interstate commerce.

With respect to the misrepresentations contained in the accompanying literature we think there can be no serious question. The two booklets, "Nutrition Guide," and "What you can do about relieving the agonies of Arthritis," were written by appellant who, in the latter, is described as "America's leading vitamin and diet expert." "Health Today, Spring 1945," is edited by the same "famous nutrition and vitamin authority." While all purport to be scientific publications of general interest apart from the articles produced and marketed by appellant, written by an expert in the field, in fact, all are replete with references to the Kordel products and their uses to prevent, ameliorate or cure a

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vast and diverse variety of ailments, and each conveniently closes with a price list of the various Kordel products recommended for use therein. All are concerned primarily with promoting the sale of the various products by explaining the need for each, along with extravagant claims as to the usefulness of each. A study of the three pamphlets reveals that the products therein described are recommended for relieving stomach agonies, general weakness, anemia, premature old age, high blood pressure, liver troubles, failing eyesight, sore feet; maintaining blood energy, muscular activity, sound teeth and gums, healthy skin, hair, and eyes; normal functioning of the pituitary and thyroid glands, stomach, intestines, colon, liver, and kidneys; and preventing arthritis and stiff joints, excess weight, catarrh, nervous break-down, sterility, and paralysis.

Thus the scheme devised by appellant for the distribution of his products and related literature contemplates an elaborate system of self-diagnosis and medication. The danger inherent in this system lies not in any positive unwholesomeness of the articles themselves. As to them as such there is no charge and it may be that they are quite harmless in and of themselves. The danger however, lies in the fact that ignorant and gullible persons are likely to rely upon them instead of seeking professional advice for conditions they are represented to relieve or prevent. The Government introduced the evidence of many very eminent men in the medical profession to prove the dangerously misleading character of the literature in that the drugs were useless to combat the conditions they were represented to relieve, while

delay in correct diagnosis and treatment for those conditions might render the treatment useless. As one of them stated, the literature encouraged people to experiment with themselves and that meant they were gambling with their health and life. Hé branded as scientifically ridiculous and nonsensical various of the claims and, when asked whether he would say that the products in themselves were harmful, replied, "They are definitely harmful in that they encourage a patient with a serious disease to experiment with himself when he should seek medical advice and precise diagnosis and therapy."

All were agreed that while the claims were absurd and fantastic, they were dangerous in that they tended to lull people into a false sense of security in reliance on the drugs when they might need professional diagnosis and treatment for conditions which might respond to treatment if correctly diagnosed early enough, but which might become much more serious if not taken care of early. Since the literature which we have already held accompanied the products embodies such misleading representations, it constitutes misbranding within the meaning of the Act.

Appellant contends that, since the current proceedings are criminal, he is entitled to a strict construction of the Act, with proof of the violation, if any, beyond a reasonable doubt. Courts for a long time have been committed to the doctrine of giving statutes intended to protect the public health a very liberal construction. As stated in Sutherland on Statutory Construction (Vol. III, sec. 7202), "The public and social purposes served by such legislation greatly exceed

the inconvenience and hardship imposed upon the individual, and therefore the former is given greater emphasis in the problems of interpretation. Therefore the courts are inclined to give health statutes a liberal interpretation despite the fact that such statutes are primarily penal in nature and frequently impose criminal penalties." To the same effect is the ruling in *United States* v. *Dotterweich,* 321 U. S. 277, where the Court said, "The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing."

We think there can be no doubt of the sufficiency of the evidence to sustain the charge beyond a reasonable doubt.

Appellant strongly relies upon *Alberty* v. *United States,* 159 F. 2d 278, to sustain his proposition that booklets and the like, not shipped at the time of the articles, do not "accompany" the article when they are introduced or offered for introduction into interstate commerce, and consequently cannot "then and there" misbrand them. The Circuit Court of Appeals for the Ninth Circuit there reversed an order overruling a demurrer to an information and remanded the cause with directions to dismiss the information. It distinguished three of the cases to which we have referred (*United States* v. *Research Laboratories, United States* v. *7 Jugs * * * Rakos,* and *United States* v. *Lee*), on the ground that all involved civil proceedings and construed the Act liberally. We have already indicated that under

the authorities cited, we do not consider the distinction applicable to the construction of the statute here involved. To the extent that the court limits the definition of the word "accompany" to mean only physical association and contiguity, we do not agree with its reasoning and are convinced that it is not in harmony with those authorities.

We find no merit in appellant's contention that he should have been prosecuted by indictment rather than by information. Section 303 (a) upon which the informations were based (21 U. S. C. A. sec. 333 (a)) provides that any person violating any of the provisions of section 201 shall be guilty of a misdemeanor, and subject to imprisonment for not more than one year or a fine of $1,000 or both, unless he has already been convicted of a prior offense under the same section. The charges were brought under this section. That being the case, there was no necessity for prosecution by indictment. See *United States* v. *Wells Co.*, 186 Fed. 248 (holding violation of the 1906 Food and Drugs Act not an infamous crime). See also *Falconi* v. *United States*, 280 Fed. 766, and cases there cited.

Judgments affirmed.

A true Copy:

Teste:

Clerk of the United States Circuit Court of Appeals for the Seventh Circuit.

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